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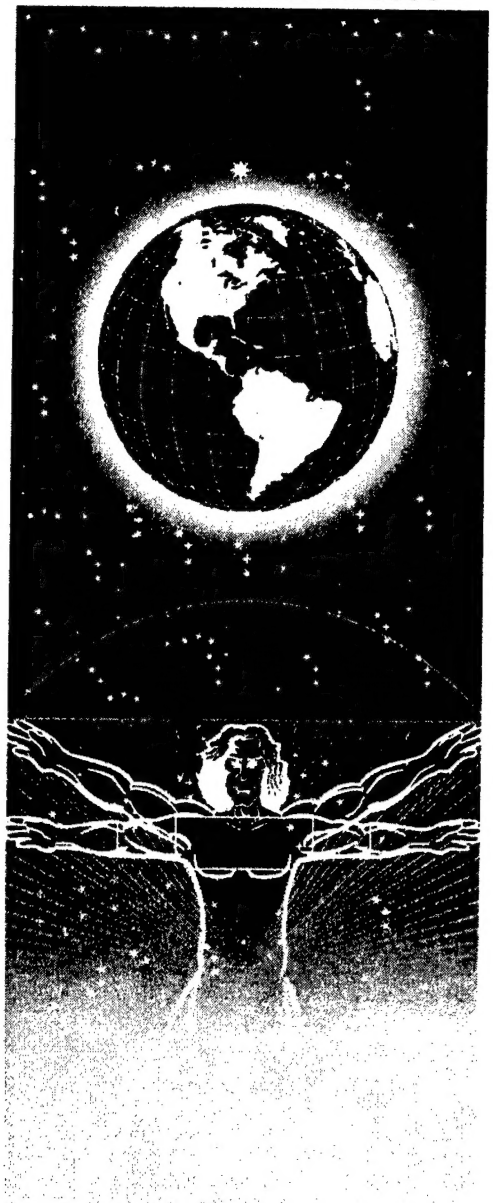

UNITED STATES AIR FORCE
AFIOH

Evaluation of Triple Containment Method for Air Transport of Contaminated Human

Lance L. Annicelli, Captain, USAF, BSC

Air Force Research Laboratory
Human Effectiveness Directorate
Biodynamics and Protection Division
7760 Chambers Parkway
Brooks City-Base TX 78235-5105

James S. Neville, Colonel, USAF
Dale D. Thomas III

August 2003

Air Force Institute for Operational Health
Surveillance Directorate
2513 Kennedy Circle
Brooks City-Base TX 78235-5116

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JAMES S. NEVILLE, Col, USAF, MC, FS
Director, Surveillance Directorate

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James S. Neville, Col, USAF
*Lance L. Annicelli, Capt, USAF, BSC
Dale D. Thomas, III.

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Air Force Institute for Operational Health (AFIOH), Surveillance Directorate,
2513 Kennedy Circle, Brooks City-Base TX 78235-5116
*Air Force Research Laboratory, Human Effectiveness Directorate,
7760 Chambers Parkway; Brooks City-Base TX 78235-5105

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13. ABSTRACT *(Maximum 200 words)*

A triple containment system intended for transport of biologically contaminated human remains was tested for its ability to maintain integrity during exposure to altitude changes representative of air transport. The system consisted of commercially available products; BioSeal® material, a Ziegler case, and a Batesville casket. Each was tested individually and as a system. The BioSeal® material was robust but did not maintain a seal in all tests. The Ziegler case was grossly unable to achieve a "hermetic" seal. The casket was not designed for air transport, but rather was fitted with manually sealable pressure equalization ports designed to be opened during flight. The proposed triple containment system was considered not suitable for air transport of biologically contaminated human remains.

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SYMBOLS, ABBREVIATIONS, AND ACRONYMS

AFEB	Armed Forces Epidemiological Board
AFIERA	Air Force Institute for Environment, Safety, and Occupational Health Risk Analysis
AFRL	Air Force Research Laboratory
CDC	U.S. Centers for Disease Control and Prevention
HRP	Human Remains Pouch
MeV	Million electron volts
RD	Rapid Decompression
Xe^{133}	Xenon ^{133}

TASKING MESSAGE

From: Archibald, Dominic D., COL, JCS J4h
Sent: 06 March 2003 9:12 AM
To: Pedersen, Kathleen M., COL, JCS J4
Subject: TRIPLE CONTAINMENT TEST

Importance: HIGH

CLASSIFICATION: UNCLASSIFIED-DRAFT

UNCLAS
MSGID/GENADMIN/-//
SUBJ/-TRIPLE CONTAINMENT TEST//
REF/A/DOC/DOD1300.22/3 FEB 00//
REF/B/DOC/JP 4-06/28AUG1996//
REF/C/DOC/DRAFT TEST PROTOCOLS/

NARR/REF A IS A THE DOD DIRECTIVE FOR MORTUARY AFFAIRS POLICY. REF B IS THE JOINT STAFF PUBLICATION PERTAINING TO JOINT TACTICS, TECHNIQUES, AND PROCEDURES FOR MORTUARY AFFAIRS IN JOINT OPERATIONS. REF C IS THE FIRST DRAFT OF PROPOSED TEST PROTOCOLS FOR THE TRIPLE CONTAINMENT TEST. POC/DOMINIC D. ARCHIBALD/COL/JOINT STAFF J4/LOC: PENTAGON 2C828/-/-//
RMKS/-
1. THE PURPOSE OF THIS MESSAGE IS TO PROVIDE INFORMATION AND DELINEATE ROLES AND RESPONSIBILITIES FOR JOINT STAFF (JS) ACTION J4A-00160-03, TRIPLE CONTAINMENT TEST.

2. CURRENT DOD POLICY OF EXPEDITIOUS RETURN OF THE REMAINS OF U.S. SERVICE MEMBERS, U.S. GOVERNMENT CIVILIAN EMPLOYEES, CONTRACTORS, AND OTHER COVERED PERSONNEL TO CONUS REQUIRES VIABLE OPTIONS FOR PROCESSING, MANAGING AND TRANSPORTING REMAINS CONTAMINATED WITH A VARIETY OF AGENTS.

3. CURRENT TECHNOLOGY PROVIDES A MEANS TO IMPROVE UPON EXISTING DOCTRINE. HOWEVER, TO ENSURE THE PUBLIC SAFETY, AS WELL AS THE SAFETY OF PERSONNEL INVOLVED IN THE HANDLING OF CONTAMINATED REMAINS, INNOVATIVE PROCESSES MUST BE TESTED FOR SAFETY AND VIABILITY. THEREFORE, THIS TASKER IS DISSEMINATED WITH SPECIFIC REQUIREMENTS FOR CONDUCTING TESTS IN ACCORDANCE WITH FINAL TEST PROTOCOLS DERIVED FROM REF. C ABOVE.

4. USTRANSCOM IS TASKED WITH COORDINATING TEST PROTOCOLS NLT 10 MAR 03 AND PROVIDING FINAL APPROVAL OR DISAPPROVAL FOR AIR AND/OR SEA SHIPMENT OF CONTAMINATED REMAINS ON USTRANSCOM ASSETS NLT 72 HOURS AFTER THE CONCLUSION OF TESTING BY THE AIR FORCE RESEARCH LABORATORY, BROOKS AFB, SAN ANTONIO, TX. TARGET

COMPLETION DATE FOR TEST IS ON OR ABOUT 14 MAR 03. AIR FORCE RESEARCH LABORATORY IS TASKED WITH ESTIMATING TEST COST (NLT 12 MAR 03), CONDUCTING THE TEST, AND PROVIDING THE RESULTS TO USTRANSCOM AND THE CENTRAL JOINT MORTUARY AFFAIRS OFFICE (CJMAO). PRELIMINARY TEST RESULTS WILL BE PROVIDED NLT 24 HOURS AFTER TESTING HAS BEEN COMPLETED. AFRL WILL FOLLOW UP WITH FORMAL REPORTS AS SOON AS POSSIBLE THEREAFTER. USTRANSCOM WILL USE PRELIMINARY RESULTS TO PROCESS ITS APPROVAL OR DISAPPROVAL DETERMINATION.

5. THE ARMY AS EXECUTIVE AGENT (EA) IS TASKED WITH PROVIDING FUNDS FOR ALL TESTS, TO INCLUDE FUNDS FOR SHIPMENT OF REQUIRED EQUIPMENT TO TEST SITE NLT 10 MAR 03. UNTIL FINANCE REQUIREMENTS ARE FINALIZED, ARMY WILL BASE BUDGET ON DRAFT PROTOCOLS, AND SHOULD INCLUDE POSSIBLE COST FOR EXPEDITIED DELIVERY, AS A BUDGETARY CONSIDERATION. ARMY POC FOR FUNDING IS LTC SCOTT DALLASSASEE, ARMY G4 FIELD SERVICES, (703) 614-4173. ARMY IS FURTHER TASKED WITH COORDINATING EQUIPMENT REQUIREMENTS AND PROCUREMENT. MATERIEL WILL BE SHIPPED TO AFRL/HEPR, BLDG 170, 2485 GILLINGHAM DRIVE, BROOKS CITY-BASE, TX 78235-5105 (FORMERLY BROOKS, AFB). ARMY POC FOR MATERIEL IS MR. BERNARD BOGAN, DSN 687-5051.

EXECUTIVE SUMMARY

In early March 2003, USTRANSCOM asked personnel from the 311th Human Systems Wing (311 HSW) and the Air Force Research Laboratory (AFRL) to quickly evaluate a system proposed to be used for air transport of biologically contaminated human remains. The evaluation was intended to demonstrate whether the proposed system would effectively satisfy requirements established by the U.S. Centers for Disease Control and Prevention (CDC) for importation of contaminated remains, namely a "hermetically sealed" triple containment system. The proposed system was evaluated under simulated flight conditions from 11 to 13 March 2003.

The proposed triple containment system consisted of BioSeal® material, sealed inside a Ziegler® case, sealed in turn inside a Batesville® casket, all commercial products. We modified a version of a protocol draft provided by the Mortuary Affairs community. The goal was to determine whether the triple containment system would maintain the three "hermetic" seals required by the CDC throughout typical air transport scenarios. The protocol was not designed to evaluate every conceivable contingency, specific material characteristics, or alternatives should the proposed system fail.

Materials were provided by Army G4 Field Services. Mortuary Affairs personnel participated and advised the testing staff on the use of materials. The system components were tested individually and together where feasible. The primary test parameter was exposure to pressure differentials as would be experienced in flight, including rapid decompression at cruise altitude. Materials were sealed at ambient altitude, about 400 feet above sea level. We attempted to simulate human remains as much as possible by using water filled balloons, but no attempt was made to quantify the starting gas volume sealed within a component.

The BioSeal® held a seal that survived exposure to 47,000 feet. On one test the BioSeal® developed a rupture during a rapid decompression, but on another test a BioSeal® pouch did not rupture even at 86,000 feet, indicating a very strong material able to withstand significant stress. We intentionally introduced contaminant materials within the seal of several pouches, such as sand, grass, and human hair; these pouches developed leaks at lower altitudes. It was observed that the integrity of the hand-sealed edges could vary due to operator performance characteristics, such as allowing the heat sealing unit to slip too quickly across the surface, allowing the material to bunch up, or allowing foreign matter on the surfaces to be sealed.

Direct observation of the construction of the Ziegler® case revealed areas that were not able to seal. We attempted to induce a pressure differential within a sealed case but were unable to achieve any differential at all. The case therefore was unable to achieve a hermetic seal even at ambient pressure.

The casket was not designed to maintain a hermetic seal while undergoing pressure changes of flight and is fitted with screw-top ports that the manufacturer's instructions stated should be opened during flight. The casket therefore would not be able to provide a hermetic seal during air transport.

In summary, the testing team found that the BioSeal® material would probably provide a hermetic seal, the Ziegler® case would not, and the casket would not during flight but could reasonably be expected to during surface transport. The proposed triple containment system should not be used for air transport of biologically contaminated human remains.

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INTRODUCTION

In early March 2003, USTRANSCOM asked personnel from the 311th Human Systems Wing (311 HSW) and the Air Force Research Laboratory (AFRL) to quickly evaluate a system proposed to be used for air transport of biologically contaminated human remains. The evaluation was intended to demonstrate whether the proposed system would effectively satisfy requirements established by the U.S. Centers for Disease Control and Prevention (CDC) for importation of contaminated remains, namely a "hermetically sealed" triple containment system as described and recommended by the Armed Forces Epidemiological Board (ref 1). The proposed system was evaluated under simulated flight conditions, from 11-13 March 2003.

The proposed triple containment system consisted of remains sealed within BioSeal®, sealed inside a Ziegler® case, sealed in turn inside a Batesville® casket, all commercial products. The human remains within the BioSeal® bag was to be enclosed in a standard Human Remains Pouch (HRP), which is a sturdy bag with a zipper closure. However, the HRP is not considered a component of the triple containment system. Given the short turn-around requested by TRANSCOM, an expedient testing protocol was developed, modified from a draft version of a protocol written by the Mortuary Affairs community. The goal was to determine whether the triple containment system would maintain the three "hermetic" seals required by the CDC throughout typical air transport scenarios. We used modified C-141 and C-17 flight profiles and included a step of exposure to heat (simulating a flight line) and a vibration table set to simulate transport aircraft. The protocol was not designed to evaluate every conceivable contingency, specific material characteristics, or alternatives should the proposed system fail.

Materials were provided by Army G4 Field Services personnel. Mortuary Affairs personnel trained in the BioSeal® sealing process performed that function and advised the testing staff on the use of the other materials. The system components were tested individually and together where feasible. The primary test parameter was exposure to pressure differentials as would be experienced in flight, as well as rapid decompression at cruise altitude. Materials were sealed at ambient altitude, which was about 400 feet above sea level. Because gases expand as altitude increases, the amount of force a material is required to withstand depends in large measure on the amount of gas sealed within the component. We attempted to approximate sealing human remains as much as possible by using water filled balloons, but no attempt was made to quantify the starting gas volume sealed within a component.

We used two methods for assessing leaks across the components. A very sensitive method was developed using Xenon ^{133}. As testing progressed, however, it became apparent that most leaks were readily apparent by either collapse of the bag or an easily observable failure of the material being tested. The Xenon method was not used in every test.

METHODS

I. Equipment/Supply Requirements:

a. Three (3) White Sheets

b. One (1) BioSeal® Containment System and associated equipment

c. Two (2) Ziegler® Cases

d. Two (2) Batesville® Caskets

e. Thirty-Six (36) pounds (12 lbs per remains) of Action Powder

f. Seventy-Two (72) pounds (24 lbs per remains) of Hardening Compound

g. Helium and Xenon^{133}

h. Helium and Xenon^{133} detection equipment

i. One (1) Forklift

II. Test Protocols:

General Procedures

Each container will be initially tested separately. If no leaks are detected then the whole system will be tested together, including the Hardening Compound and Active Powder. Each component will be subjected to heat, vibration, and pressure stresses as described below. A test will be considered successful if no leak of the test gas is detected.

a. <u>BioSeal® Containment System Test Protocol</u>

1. After insertion of a specified amount of test gas, the three (3) open sides of a BioSeal® Containment System will be sealed with a Heat-Sealer set to a temperature of approximately 350 degrees Fahrenheit to hermetically seal the bag. The Heat Sealer will be moved across the BioSeal® material at approximately one (1) inch per second, with approximately 25 to 28 pounds of pressure exerted on the handle of the Heat-Sealer; about the amount of pressure used when shaking hands, to effectively seal the material. Two (2) seals will be created around each of the open sides approximately one (1) inch apart. The second seal is added as a safety measure to ensure the integrity of the containment system in case the first seal leaks.

2. The BioSeal® Containment System will then be subjected to the chamber flight plan (see Appendix A).

3. The BioSeal® bag will be checked for leaks using the method described in Appendix B.

b. Ziegler® Case Test Protocol

1. The test gas will be injected into a Ziegler® case and the lid screwed tightly into place, hermetically sealing the Ziegler® case.

2. The Ziegler® case will be subjected to the flight plan (see Appendix A).

3. The case will be checked for leaks using the method described in Appendix B.

c. Batesville® Casket Test Protocol

1. The test gas will be injected into a Batesville® casket. The lid of the casket will be closed, locked, and tightened to hermetically seal it.

2. The Batesville® casket will be subjected to the chamber flight plan (see Appendix A).

3. The casket will be checked for leaks using the method described in Appendix B.

d. Drop Protocol

1. After successful completion of a total containment system has been accomplished, a Ziegler® system (sealed BioSeal® bag inside a sealed Ziegler® case inside a sealed Batesville® casket) will be raised to a height of 4 feet and dropped onto a cement surface. This action is designed to simulate the unlikely event of a forklift dropping the system during movement on a ship or into an aircraft and control being lost.

2. The casket will then be tested in the altitude chamber as described in Appendix A.

III. General Test Procedures:

a. At the end of each testing cycle, each piece of equipment tested will be graded as "leak detected" or "no leak detected".

b. Between tests the altitude chamber must be vented to purge it of any potential test gas residuals to prevent the leak sensors on the follow-on Test Protocols from registering positive from residual gas fumes. In the event that a leak is detected, an attempt will be made to identify the component that failed.

c. Records will be kept of each phase of the tests.

d. Each test (BioSeal®, Ziegler® case, and Batesville® casket) will be performed a minimum of three times each as time allows. Simulation variances in protocol design are acceptable, but must be documented, to facilitate actual flight replication. Standard for test results is zero (0) deficiencies (no leaks).

Appendix A: Chamber Flight Profile (includes heat, vibration, and pressure components)

1. Heat Exposure of container being tested: Simulates time spent on the tarmac (recognizing that heating of the BCS would not necessarily be the same if it were contained in the Ziegler® case and casket)

a. "E chamber" pre-heated to 120 degrees F
b. Altitude: ground level pressure
c. Heat exposure duration: 60 - 120 minutes (requires feedback from mortuary affairs on a realistic time)
d. AFIERA tests leaks according to the protocol in Appendix B or C.
e. At the completion of the exposure period, if no leak is detected, the container and the litter are transported to the vibration table. If a leak is detected, the test may continue but the test operator will determine whether the container needs to be refilled with the test gas before proceeding.

2. Vibration test to simulate vibratory stresses of flight:

a. Litter and container are strapped to the vibration table
b. AFIERA tests container for leaks once it is secured (see Appendix B or C)
c. Vibration profile conducted (profile represents a generic jet engine profile used by the HSW aeromedical equipment test function - 30 minute test per axis)
d. After completion of the profile, AFIERA again tests the container for leaks
e. At the completion of the vibration test, if the BCS rating is PASS, it and the litter are transported to the altitude chamber. If a leak is detected, the test may continue but the test operator will determine whether the container needs to be refilled with the test gas before proceeding.

3. Altitude Exposure of Containers being Tested:

a. Container and litter are placed inside C-chamber in the mid-lock
b. Door to the main chamber compartment is left open
c. AFIERA tests container for leaks prior to ascent
d. Flight Profile:
1) Ascent from ground level to 8,000 feet at 1,000 feet/minute
2) Maintain 8,000 feet altitude for one hour
3) At one-hour point, conduct rapid decompression from 8,000 to 37,000 feet (decompression rate will be approximately 10 seconds)
4) Maintain 37,000 feet for one minute (longer if AFIERA needs more time to complete a leak test)
5) After one minute at peak altitude, descend to 10,000 feet at 10,000 ft/minute
6) At 10,000 feet, slow descent rate to 2,000 ft/min, stopping the descent at 4,000 feet
7) Maintain 4,000 feet for 30 minutes
8) Descend to ground level at 2,000 ft/min
e. Leak checks will follow the procedures in Appendix B or C.
f. After completion of the altitude tests, the manikin (if used) will be removed from the container. Each BioSeal® System will be used only once and will not be used for a second test of any kind; the Ziegler® case and casket may be re-used.

g. For testing the Ziegler® case and the casket, a port may be installed that can be used to introduce the test gas to a pressure that will result in a pressure differential to simulate the flight profile up 45,000 feet. This will allow the leak testing to occur outside the chamber at ground level.

h. Several smaller BioSeal® bags ("pillows") will be tested within the chamber under different conditions. For example, intentionally leaving a small gap in the thermal seal process, placing a human hair across the area to be sealed, placing a small amount of dirt across the area to be sealed, taking the sealed bag to the max altitude to test bursting thresholds, etc.

Appendix B: Leak Testing Protocol: Helium

1. BioSeal® bag

a. Sensor preparation

1) The thermal conductivity helium-sensing unit will be turned on at least 5 minutes prior to the start of the experiment and will be considered ready when the zero alignment is stable.

2) The probe line of the thermal conductivity helium-sensing unit will have been previously sealed in a penetration into the chamber.

3) Upon placing the dual bag system (described below) into the chamber the probe end will be placed partially through the opening of the second bag.

b. Bag preparation

1) All but one inch of the BioSeal® bag will be sealed.

2) The bag will then be flushed with helium.

3) The final sealing will then be accomplished.

4) A second bag, slightly larger than the first, will then be placed around the first bag leaving an approximately 1 inch opening in the seam.

5) The bag unit will then be subjected to the exposures as per Appendix A. (See also a.3. above)

2. Human Remains Pouch and Ziegler® Case

a. A hermetically sealed valve and pressure gauge unit will be attached to the Ziegler® case holding the Human Remains Pouch (HRP) with Biosealed simulated remains.

b. Initially, the units will be flushed with helium and then sealed according to the manufacturer's usual specifications.

c. Helium will then be introduced into the chamber until the pressure differential is equal to the test altitudes.

d. The probe of the leak detector (after having stabilized the zero setting) will be hand drawn across the bag/casket seals to initially determine if there are any leaks.

e. Flight simulation will then be conducted according to Appendix A.

f. At the end of the test the probe will again be hand drawn across the HRP/Ziegler® case seals to determine if any leaks can be detected. This can be accomplished at intervals during the test as well if necessary. After the pressure returns to baseline, the container will be opened with the probe near the opening to verify the sensor's ability to detect helium.

Appendix C: Leak Testing Protocol: Xenon^{133}

1. The container being tested is injected with Xenon-^{133} (Xe-^{133}). Xe–^{133} is a radioactive noble gas that will rapidly become uniformly distributed throughout the space in the container. A high-purity germanium detector (HpGe) will be used to effect measurements of the Xe-^{133} gamma spectrum (principally the 0.081 MeV photon with an intensity of 38%).

2. Before commencing with each respective test phase, an initial measurement of the container is made to determine optimum measurement distance and establish the baseline or reference activity before commencing with the test phase. The container is then released to the chamber investigators for completion of the individual test phase (i.e. vibration, thermal, or pressure differential).

3. At the conclusion of the testing phase, the HpGe detector is used to measure the Xe-^{133} remaining in the tested container. If the Xe-^{133} measured value remains constant across a series of tests, the test did not result in a breach in container integrity. Reduction of the post-test measurement Xe-^{133} relative to the initial measurement indicates that the container developed a leak during the test.

RESULTS

The following supplies were received on 10 Mar 03:

2 Batesville® caskets
2 Ziegler® containers
100 feet of BioSeal® material
2 hand held heat-sealing devices
Viscerock preservative powder and hardening compound
Action and embalming powder
2 sheets
2 blankets
2 Human Remains Pouches (HRP)

Inspection/observation of the two Batesville® caskets revealed the following:

1. The package insert within the Batesville® casket indicates that it is possible that the casket will collapse if it is subjected to significantly different atmospheric pressures after it has been sealed. Therefore, if casket is to be transported by air or at higher altitudes, it is necessary to equalize the pressure between the inside and outside of the casket. To accomplish this, the screw cap must be removed thereby venting the casket.

2. The rubber casket seal was not aligned with contours between both lid and base of casket.

Inspection/observation of the inner Ziegler® containers revealed the following:

1. Both Ziegler® containers within each of the two caskets had several small openings where the metal corners did not close during the manufacturing process.

2. Sharp edges from predrilled holes in the top of the case has potential of cutting HRP and/or BioSeal® material.

3. Several small sharp pieces of metal shards protruded from the bottom of the Ziegler® container.

4. Black foam type material lining the lid of the Ziegler® container appeared to be misaligned and offset.

5. Predrilled holes for sealing Ziegler® containers were not aligned properly between the lid and container, so that the screws would not be able to be screwed in perpendicular to the surface.

6. Large gaps existed between the lid and container prior to tightening of screws.

7. Size of Ziegler® container was questioned...could not fit one of our AF members into container.

8. The lid was designed to be held in place by simple sheet metal screws, not bolts or brackets.

BioSeal® Material Seal Check

Several pillow sized (approx 18" x 18") BioSeal® test bags were subjected to altitude chamber decompression to assess the location and stress of rupture at altitude. An assortment of possible contaminants was introduced individually between the edges to be sealed in an attempt to simulate possible field conditions. Placed within each bag was a folded sheet to represent contents and allow the introduction of residual air within the sealed bag. Results from testing of the small pillow sized bags should not be interpreted as representing expected results from a full size (human remains size) due to the increased volume of trapped air/gas, which would accompany a larger mass. The dynamics of different size bags may be quite different. Small pillow sized bags were tested simply to get a feel for the strength of the seals over a wide variety of possible scenarios.

Contaminant	Observation
No contaminant	No rupture (67,000 ft)
Human hair crossing the double heat seal	Ruptured at seam, not on hair
Sand within the seal	Leaked at point of sand contamination
Grass and material crimped /folded within seal	Burst at approx 50,000 ft near crimp
Preservative powder and hardening compound within seal	Leaked at approx 40,000 ft (note: small pillow sized container developed a leak at 40,000 feet and then re-inflated followed by a deflation at a constant altitude. This cycle continued indicating a possible off-gassing from powder substance).
Super heated/brittle seal	No rupture (86,000 ft)

Ziegler® Container Leak Check

AFRL personnel drilled a hole within the side of Ziegler® container to create a port to both introduce pressure and check for leaks. An attempt was made to seal the Ziegler® container lid using the screws that were provided. Several predrilled holes for the metal screws were not aligned properly between the lid and container. Screws were hand-fastened using a Philips head screwdriver and did not appear to provide adequate tension between the lid and container. The testing team was unable to obtain a visual seal on the Ziegler® container. The screws were tightened more firmly to attempt a better seal, resulting in at least one screw becoming stripped. A leak detector solution (soap and water) was used to test the lid seal. Ziegler® container was positioned upside down to allow visual inspection for leaks.

Observations: Team was unable to hermetically seal Ziegler® container using material provided by the manufacturer (i.e. screws). Additionally, the team was uncertain how tight to turn the screws to obtain the optimum seal or how tight the screws could be turned before over-tightening and stripping the screw.

Results: Numerous bubbles were identified around the entire lid and between edges of metal container, confirming the visual observation of leaks. (See Figure 6)

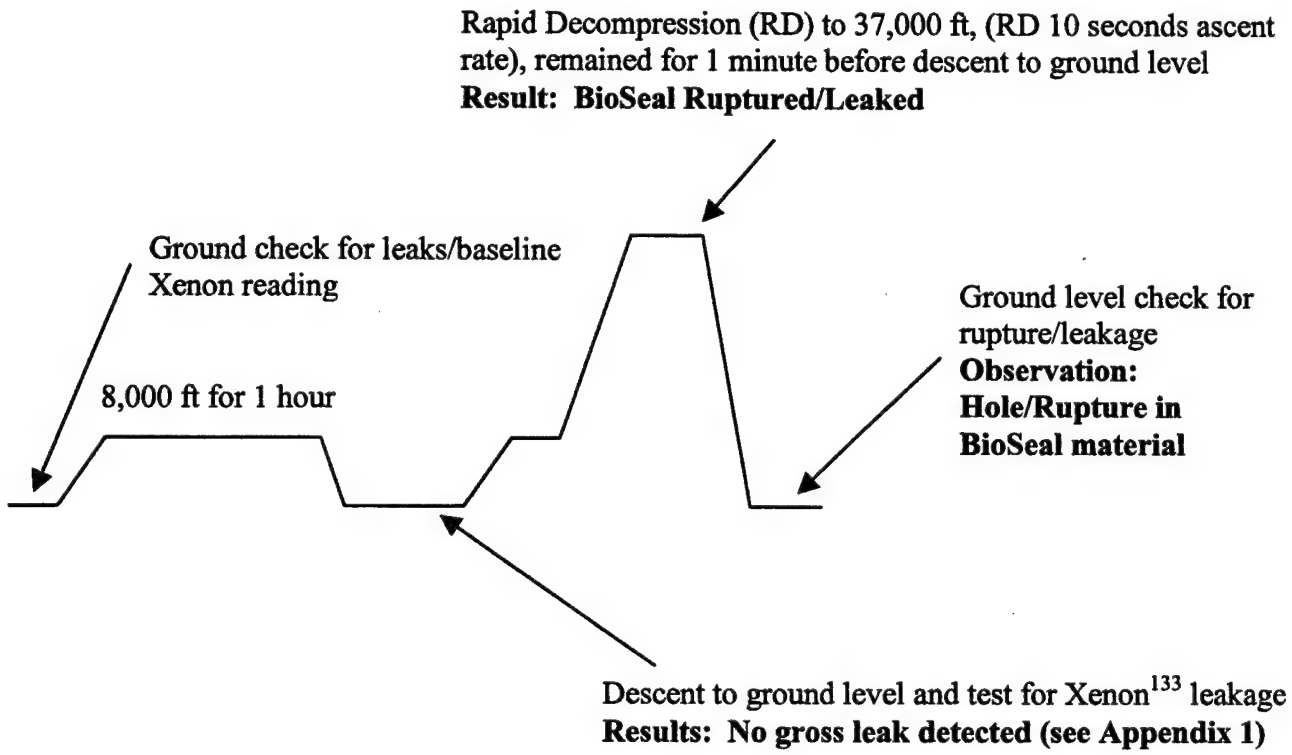
BioSeal® and Human Remains Pouch Rapid Decompression/Ascent to 37,000 Feet

Trained personnel from Mortuary Affairs placed a mannequin wrapped within a sheet inside the BioSeal® material. The BioSeal® material with simulated remains and a source of Xenon^{133} was sealed according to manufacturers instructions. The BioSealed mannequin was placed into a Human Remains Pouch (HRP) and then moved into the altitude chamber according to the established protocol. The protocol initiated a 1000 foot per minute ascent to 8,000 feet for 1 hour, then descent to ground level for measurements, then again back to 8,000 feet. After achieving a pressure altitude of 8,000 feet, the remains were subjected to a rapid ascent to 37,000 feet (approximately 10 seconds). The pressure altitude of 37,000 feet was held for 1 minute before descending to ground level.

Observations: During rapid ascent/RD the HRP and BioSeal® material expanded and then visibly deflated indicating a rupture.

Results: Visual inspection after the chamber flight revealed a rupture within the BioSeal® material.

Limitations: The mannequin that was used was largely hollow, though not completely. This resulted in a larger volume of gas than might be expected with human remains. However we did not attempt to measure the volume of gas within the sealed bag. Since there was no way to estimate the volume to be expected within a bag in operational use, measuring the volume of gas was not felt to be necessary. Additionally, the team was uncertain how much off-gassing might occur with human remains sealed within the BioSeal® system.

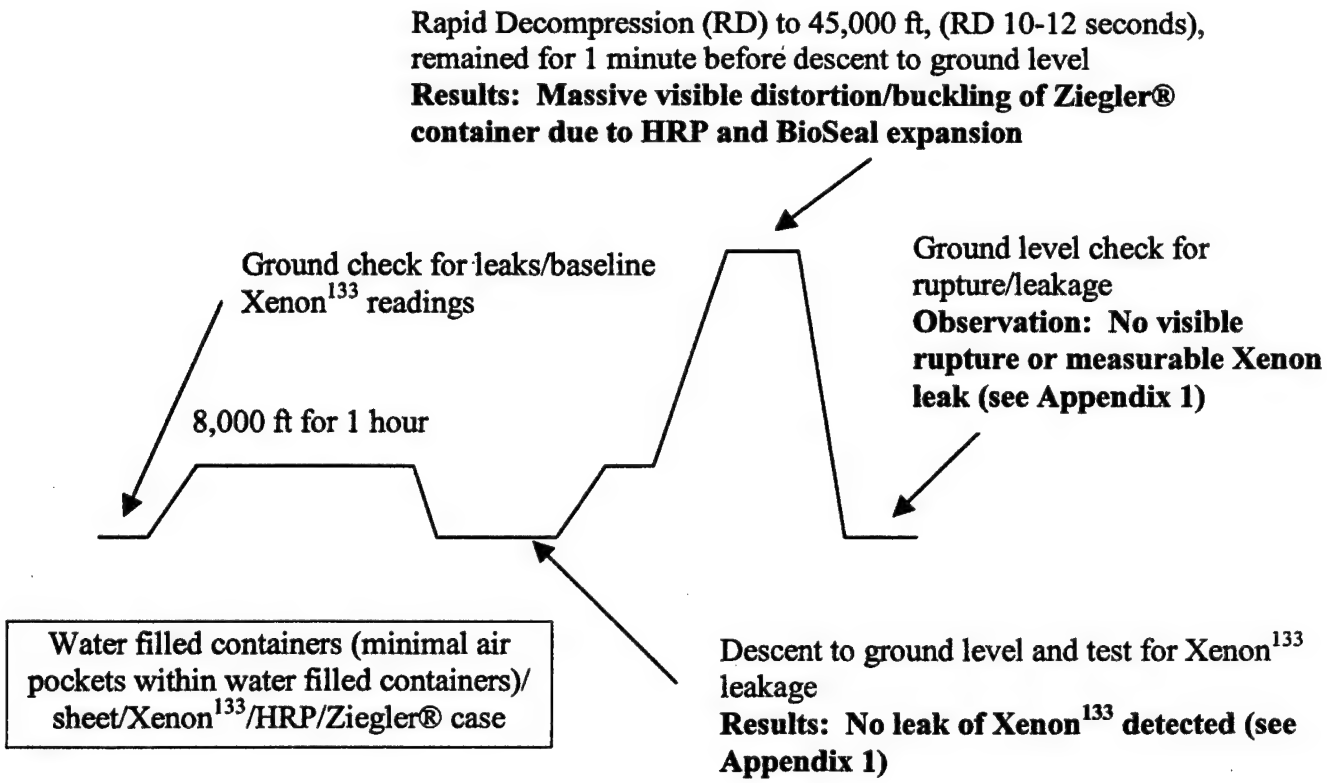


BioSeal, HRP, and Ziegler® Container Rapid Decompression/Ascent to 45,000 Feet

Mortuary Affairs personnel wrapped 4 cylindrical water bladders (approximately 200 lbs) within a sheet to simulate remains. Water bladders were used to reduce the amount of air to be trapped within the BioSeal® envelope. Both remains and sheet were then placed into the BioSeal® material. The BioSeal® material with simulated remains and source of $Xenon^{133}$ were sealed according to manufacturers instructions. The BioSeal® with simulated remains were zippered into a Human Remains Pouch (HRP) and then placed into a Ziegler® container. The Ziegler® container was sealed with the accompanying sheet metal screws then placed into the altitude chamber. The protocol initiated a 1,000 foot per minute ascent to 8,000 feet for 1 hour, then descent to ground level for leak measurements, then again back to 8,000 feet. After achieving 8,000 feet pressure altitude, the remains were subjected to a rapid ascent to 45,000 feet (ascent duration of approximately 10-12 seconds). The pressure altitude of 45,000 feet was held for 1 minute before descending to ground level.

Observations: During rapid ascent the HRP and BioSeal® material expanded causing the Ziegler® case to buckle and deform. The lid of the Ziegler® container had physically separated from the lower portion of the container. There was no apparent rupture of the BioSeal® material post RD inspection.

Results: The integrity of the Ziegler® container was compromised by the inflation of the BioSeal® and Human Remains Pouch. No $Xenon^{133}$ leak was detected.

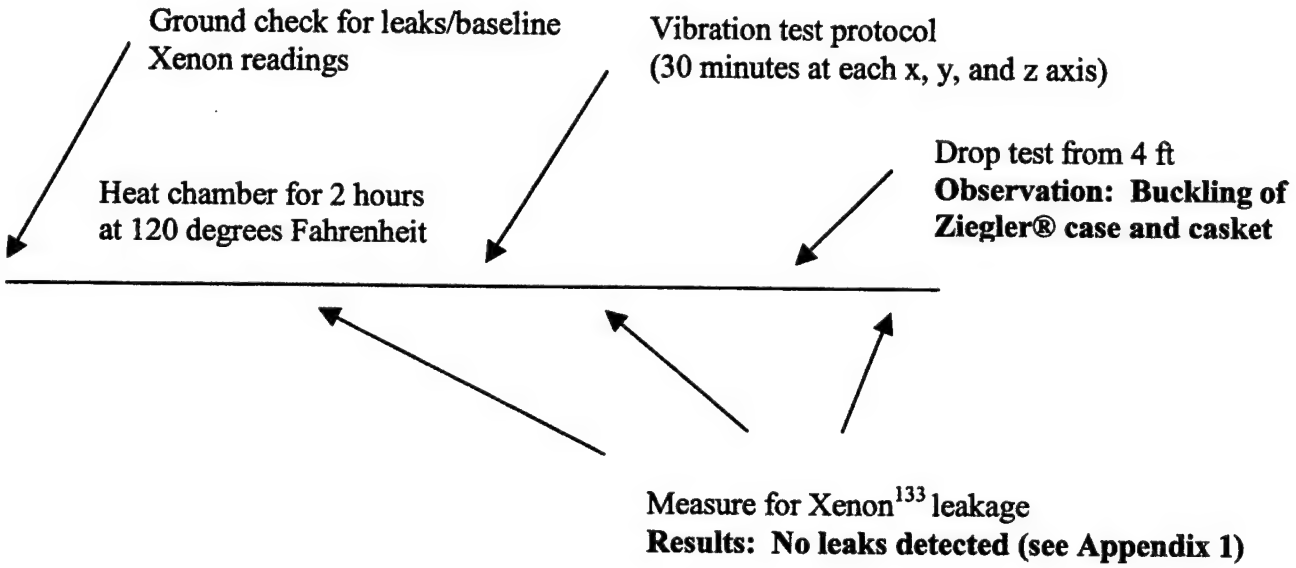


Heat and Vibration Testing of Triple Seal Containment System

Mortuary Affairs personnel wrapped 4 water bottles (approximately 160 lbs) within a sheet to simulate remains. Both remains and sheet were then placed into the BioSeal® material. The BioSeal® material with simulated remains and a source of $Xenon^{133}$ were sealed according to manufacturers instructions. The BioSeal® and simulated remains were placed into a Human Remains Pouch (HRP) and then placed into a Ziegler® container. This in turn was placed into the Batesville® casket. All three containers to include the BioSeal/HRP, Ziegler® container, and Batesville® casket were then measured for a base line reading of $Xenon^{133}$. The triple containment system was then placed into a heat chamber for 2 hours at 120 degrees Fahrenheit. Following the heat chamber treatment, the triple seal system was measured for any $Xenon^{133}$ leakage. The entire system was then subjected to 1.5 hours of constant simulated aircraft vibration according to Mil-Std 810F covering all three axes (see Figure 7). Upon completion of vibration testing, the triple seal containment system was again measured for $Xenon^{133}$ leakage.

Observations: Post vibration inspection revealed no damage to interior or exterior of either the Ziegler® container or Batesville® casket as a result of heat or vibration.

Note: Test team was unable to attain a hermetic seal on Ziegler® container due to manufacturer defects between lid and container on any of the testing trials.



Complete system consisting of 160 lbs bottled water (simulated human remains)/sheet/$Xenon^{133}$/BioSeal®/HRP/Ziegler® case/Batesville® casket

Drop Test of Triple Seal Containment System

A four-foot drop test was conducted using the entire Triple Seal Containment System from the heat and vibration study used on 12 March 2003. All three containers to include the BioSeal®/HRP, Ziegler® container, and Batesville® casket were measured for a baseline reading of $Xenon^{133}$. A forklift was used to raise the triple containment system to height of 4 feet. The system was then dropped onto the pavement. Three separate drops were performed. The Triple Seal Containment System was then subjected to measurements for any $Xenon^{133}$ leakage.

Observations: Significant damage occurred during all three drops. Damage to outside casket revealed a compromised lid allowing a visual opening into the inner containment area of the casket. The inside Ziegler® container buckled from the weight and movement of the 160 pounds of water. The metal container was physically bent and separated from its lid exposing the HRP.

Results: Visible damage to both metal Ziegler® and Batesville® containers compromised the integrity of the containment system. There was no detectable leak of $Xenon^{133}$ from the BioSeal® container.

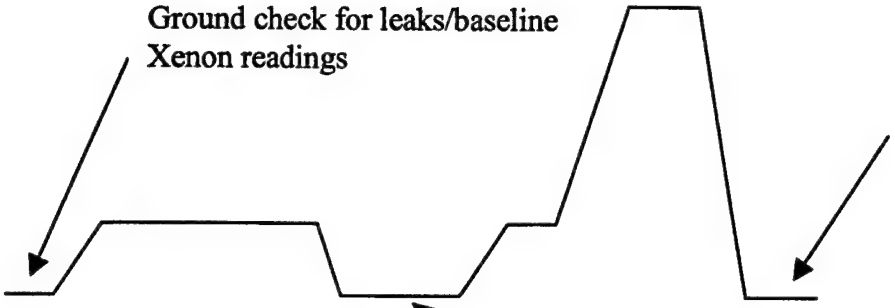
BioSeal, HRP, Ziegler® Container, and Batesville® Casket Rapid Decompression/Ascent to 45,000 Feet

The BioSealed simulated remains along with the Human Remains Pouch from the RD to 45,000 trial was used in combination with the complete system of a Ziegler® container and Batesville® casket. The casket was allowed to vent by removing the screw cap according to the Batesville® casket manufacturers instruction. This allowed for the pressure to equalize between the inside and outside of the casket. The flight profile consisted of a 1,000 feet per minute ascent to 8,000 feet pressure altitude for one hour and a rapid decompression to 45,000 feet (rapid ascent rate of approx 10-12 seconds) for one minute before descending to ground level.

Observations: During the rapid ascent the HRP and BioSeal® material expanded due to the volume of gas expansion within the BioSealed simulated remains, causing the Ziegler® case to buckle and deform within the casket. The lid of the Ziegler® container physically separated from the lower portion of the container. There was no apparent rupture of the BioSeal® material post RD inspection.

Results: The integrity of the Ziegler® container was compromised by the inflation of the BioSeal® and Human Remains Pouch. There was no detectable leak of $Xenon^{133}$ from the BioSeal® container.

Rapid Decompression (RD) to 45,000 ft, (RD 10-12 seconds), remain for 1 minute before descent to ground level
Results: Massive visible distortion/buckling of Ziegler® case due to HRP and BioSealed remains expansion. No visible detection of BioSeal® rupture. No damage to Batesville® casket because of intentional pressure venting between the inside and outside of casket.



Ground check for leaks/baseline Xenon readings

Ground level check for rupture/leakage
Observation: No visible rupture or measurable Xenon leak (see Appendix 1)

Descent to ground level and test for Xenon leakage
Results: No leakage of Xenon^{133} detected (see Appendix 1)

Full triple containment system consisting of casket, Ziegler® case, human remains pouch, sheet, and simulated remains (approximately 160 lbs water). Water filled containers (no air pockets within water filled containers)/ sheet/HRP/BioSeal® bag/Xenon/Ziegler® case

Batesville® Casket Altitude Testing with Screw Cap in place

Pressure changes were measured within the Batesville® casket with the pressure screw cap in place against the manufacturer's recommendation, which required removal prior to air transportation. A pressure sensor was placed in the casket through an existing port. The casket was placed in the altitude chamber. The chamber was manually ascended/descended and results observed.

Observations: Casket seals allowed for air to escape while ascending. This was further observed with the pressure fluctuations while air burped out of the sealed casket. Once at altitude the casket was subjected to a rapid descent. The descent phase of the flight caused the casket to implode.

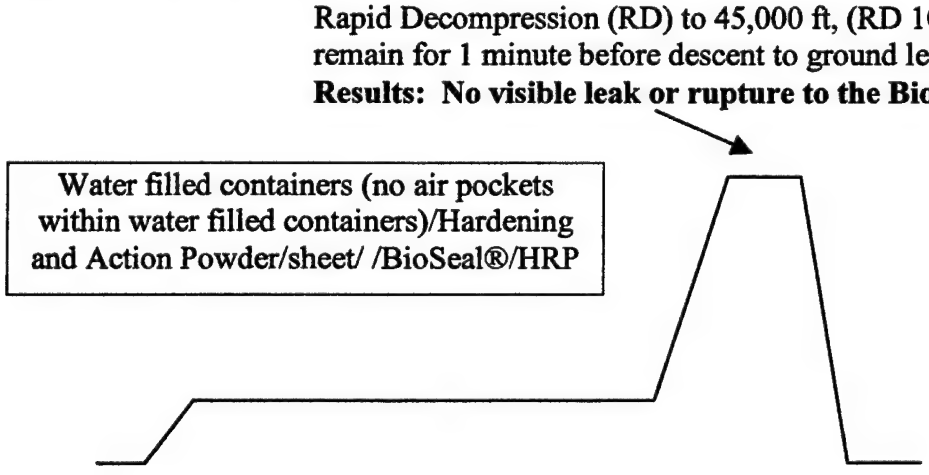
Results: Leaving the vent screw in place caused the casket to implode on descent, verifying the manufacturer's manual.

BioSealed Simulated Remains along with Hardening and Action Powder, and Human Remains Pouch Rapid Decompression/Ascent to 45,000 Feet

Mortuary Affairs personnel wrapped 3 cylindrical water bladders (approximately 160 lbs) within a sheet to simulate remains. Water bladders were used to allow a minimum amount of air to be trapped within the BioSeal® envelope. Hardening and Action Powder was used to approximate the amount used for actual remains. This was used to simulate the potential source of contamination while achieving a hermetical seal between the two layers of BioSeal® material. The simulated remains wrapped in a sheet were then placed into the BioSeal® material and sealed. No $Xenon^{133}$ was used. The BioSealed remains with Hardening/Action Powder were placed into a Human Remains Pouch (HRP). The HRP was then placed into the altitude chamber according to continuously modified protocol. The protocol initiated a 1,000 feet per minute ascent to 8,000 feet for 1 hour, then a rapid ascent to 45,000 feet (ascent duration of approximately 10-12 seconds). The pressure altitude of 45,000 feet was held for 1 minute before descending to ground level.

Observations: A noticeable volume expansion occurred with the BioSeal® and HRP but did not appear to have leaked or ruptured because the system maintained its "ballooned out" appearance while at altitude.

Results: No leaks were detected visually.



DISCUSSION

In this abbreviated testing session, the BioSeal® material held up quite well, although the protocol was not designed to thoroughly test the material. We attempted to conduct some tests with what we thought might be reasonable contaminants across the seal surfaces. These contaminants appeared to affect the ability of a sealed bag to withstand pressure changes, but a definitive judgment on this topic is not possible from this limited testing.

Even in the hands of experienced operators, the sealing process appeared problematic. The heated sealing mechanism sometimes slid across the material unevenly, bringing into question the integrity of the seal. We attempted to overheat the seals of a small pouch by intentionally leaving the sealing mechanism in place too long. This pouch survived a very high altitude exposure.

The construction of the Ziegler® case did not allow a "hermetic" seal. We attempted to assess the ability of the case to withstand pressure differentials by drilling a hole in the side, then installing and then sealing a port through which a pressure transducer was placed. We could not produce any measurable pressure differential because the entire area of the lid-case interface leaked (see figure 6). We determined that the Ziegler® case could not be relied upon as a "hermetic" seal.

The Batesville® casket was designed with two access ports with screw-on seals. The manufacturer's instructions direct that these ports are to be opened during flight in order to avoid failure of a casket exposed to pressure differentials of flight. We tested this by sealing a casket, taking it relatively slowly to 47,000 feet, then returning it relatively quickly to ground level. The casket was able to maintain only a very small pressure gradient during ascent, and when the altitude was maintained this gradient slowly approached zero, indicating that the casket was unable to maintain a "hermetic" seal when exposed to pressure changes. Upon descent, the casket imploded as predicted by the manufacturer.

We did not test the ability of 3 BioSeal® bags together to hold a seal, since that was not the procedure established by Mortuary Affairs and we felt that the width of the BioSeal® material would make 3 consecutive seals functionally impossible to achieve. We were not able to comment on whether the proposed triple containment system would be an effective method for surface transport by ship. Ships have their own vibration and other environmental considerations and we are not equipped for the appropriate tests.

CONCLUSION

It can confidently be said, that the proposed triple containment system would not provide the triple containment required by the CDC, and that the system would not provide adequate protection for transport aircraft aircrew or passengers.

RECOMMENDATION

The proposed triple containment system should not be used for air transport of biologically contaminated human remains.

EVALUATION PERSONNEL

Project Officer-AFIOH/SD
Col James Neville

AFRL/HEPR personnel directly and indirectly involved with evaluating/testing of the Triple Containment Method:

Capt Lance Annicelli (Co-author)
TSgt Danelia Chappell
Mr Tommy Miller (Contractor)
Mr Nathan Dillon (Contractor)

Altitude Chamber Operations (AFRL/HEPR)
MSgt Stanley Skou
Mr Jim Carlile (Contractor)
TSgt Sam Colon
SrA Vontez Morrow
TSgt Kevin Johnson
TSgt William Tucker
SrA Leo Funchess

311 HSW/YAML personnel involved with the vibration test protocol of the Triple Containment Method:
MSgt Robert Eshelman
Mr Victor Elizondo

The following AFIOH/SDC and SDRR personnel were involved with the leak testing measurements of the Triple Containment Method:
Capt Bruce Goplin
Mr Dale Thomas (Civilian, Co-author)
MSgt Dave Mann
Dr George Lee (Civilian)

311 HSW/PA
SSgt John Jung provided over 200 photos documenting the entire process of testing and evaluation

AFRL/HEPR personnel indirect/behind the scenes involvement:
Maj Robert O'Connor
1Lt James Kisner

Visiting personnel involved with direct evaluation/testing of the Triple Containment Method:
Mr Garold "Gary" D. Huey, Senior Mortuary Specialist Air Force Mortuary Affairs
Mr Douglas L. Howard, Deputy Director, U.S. Army Mortuary Affairs Center

FIGURES

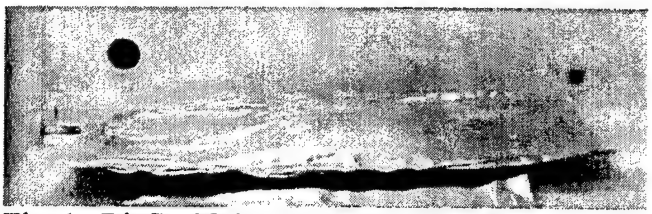


Fig. 1. BioSeal® bag at ground elevation

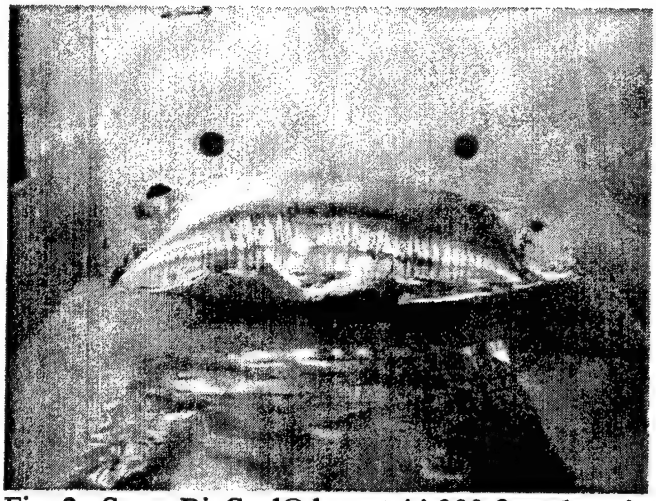


Fig. 2. Same BioSeal® bag at 44,000 feet elevation; note expansion. The degree of expansion will depend on the volume of gas sealed within the bag and the ambient pressure or altitude.

Fig. 3. Ziegler® case containing a BioSeal® bag inside a Human Remains Pouch, rapid decompression to 45,000 feet elevation; note buckling, possibly restrained by litter straps.

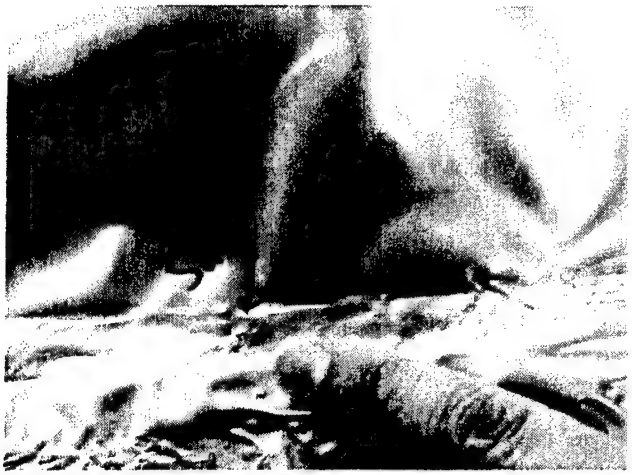


Fig. 4. Sand intentionally placed in seal; this bag leaked throughout ascent in the chamber

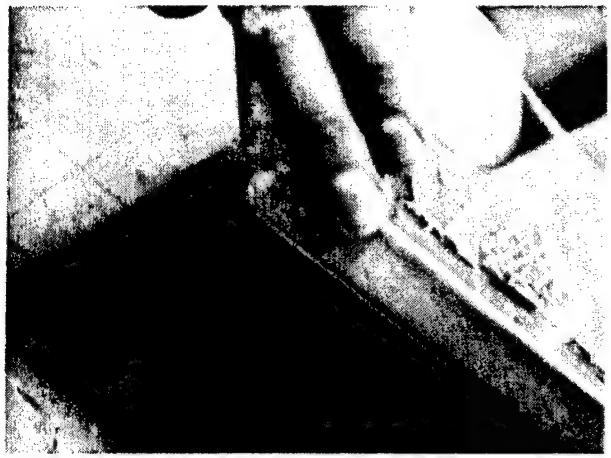


Fig. 5. Pinhole on edge of previously unused Ziegler® case; hole is outside the area designed for the gasket on the lid

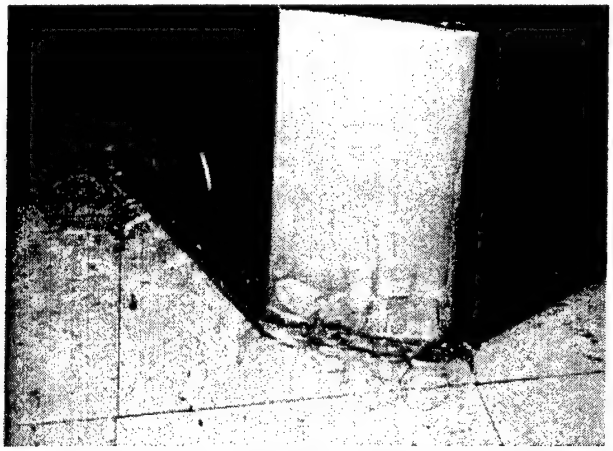


Fig 6. Attempt to produce a pressure differential within the Ziegler® case was unsuccessful; gas leaked around the entire lid as evidenced by these bubbles

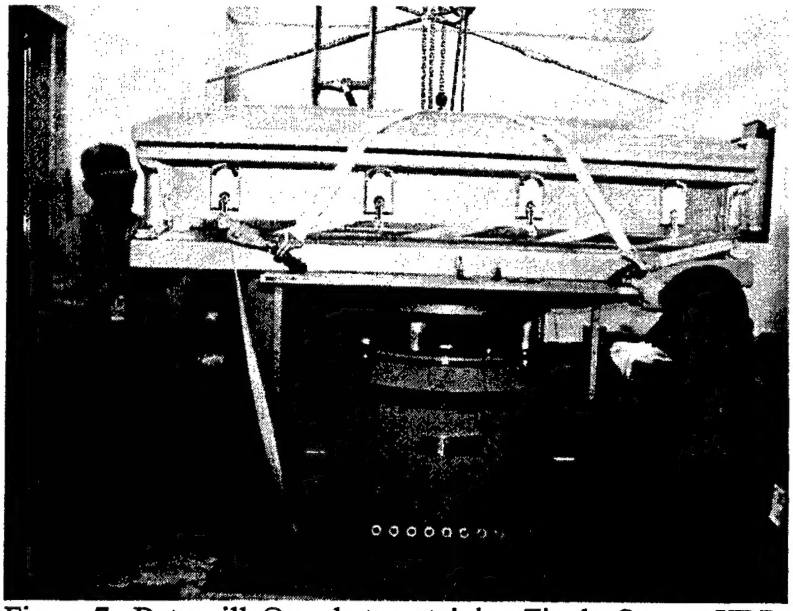


Figure 7. Batesville® casket containing Ziegler® case, HRP, and BioSeal® bag on a 3-axis vibration table

REFERENCES

1. Memorandum, Armed Forces Epidemiological Board, for Assistant Secretary of Defense (Health Affairs), "Disposition of Contaminated Human Remains 2003-2006", dated 14 January 2003.

2. Joint Publication 4-06 "Joint Tactics, Techniques, and Procedures for Mortuary Affairs in Joint Operations.

APPENDIX A

Triple Containment Evaluation Using Xenon^{133}

A1. From 11-13 Mar 03, Mr. Dale Thomas, Capt Bruce Goplin and MSgt Dave Mann from AFIERA/SDRR evaluated the BioSeal® containment system for potential leakage using Xenon^{133} (Xe-133). A series of stress tests were performed to simulate extreme conditions that could potentially be encountered such as a sudden aircraft cabin pressure loss, vibration, high temperature and dropping of the casket.

A2. Methodology. A radioactive noble gas Xe-133 was injected into the BioSeal® hazard bag to assess potential leakage. Xe-133 is a short-lived (5.25 day half-life) gamma-emitting isotope with the principal photon of interest being 0.081 MeV and an abundance of approximately 37 percent. After injection, Xe-133 rapidly became uniformly distributed within the bag. Baseline measurements were collected at fixed geometries (~100 inches from the BioSeal® bag) to determine initial Xe-133 activity. Measurements where then collected at the same geometries after each simulated test condition to assess a change in activity. Two control bags were also tested that were not subjected to simulated test conditions. Measurements were made with a high-purity germanium detector (HpGe) and the Canberra Digital Inspector 2000 Spectrum Analyzer. See section II of the test protocols for additional details.

A3. Results. Measurements during various phases of the test did not demonstrate statistically significant changes in Xe-133 activity; thus suggesting leaks were not detected. A general downward trend was noted between measurements that cannot be accounted for by radioactive decay. This trend was also noted in the control bag. This could indicate the presence of minor leaks and/or diffusion of xenon through the BioSeal® bag. Chart 1 provided below identifies relative Xe-133 activity before and after altitude testing. Chart 2 shows relative Xe-133 activity before and after the following test protocols: elevated temperature test, vibration stress test and a four-foot drop test. Note that the error bars indicate the 95 percent confidence interval associated with each test (mean +/- 1.96 standard deviations).

Chart 1. Evaluation of BioSeal® Bag - Altitude Test Protocol

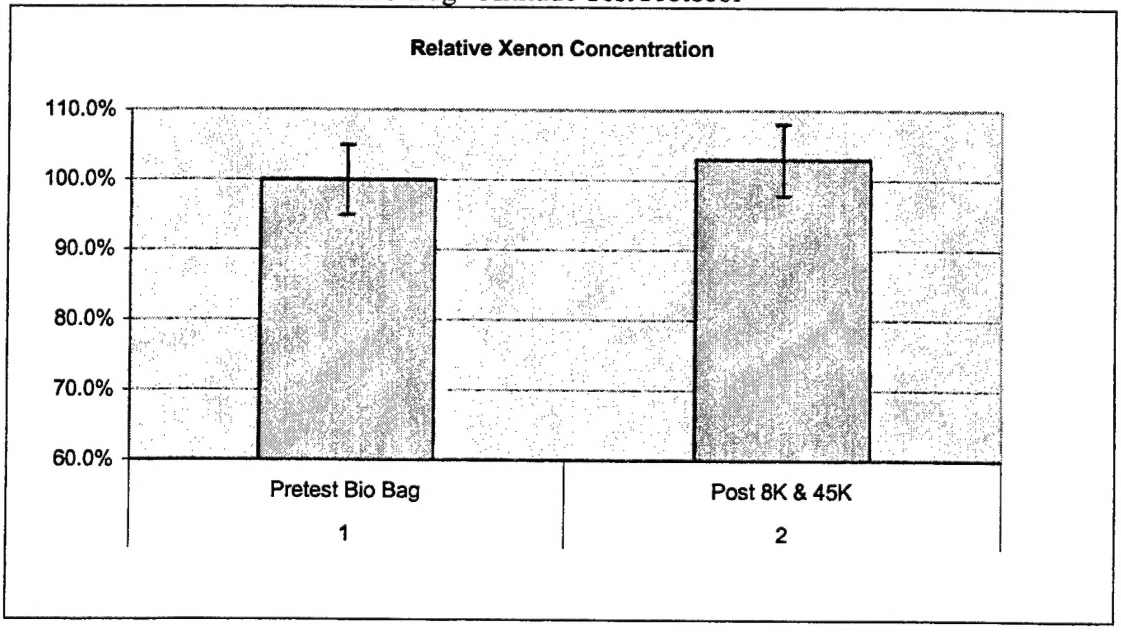
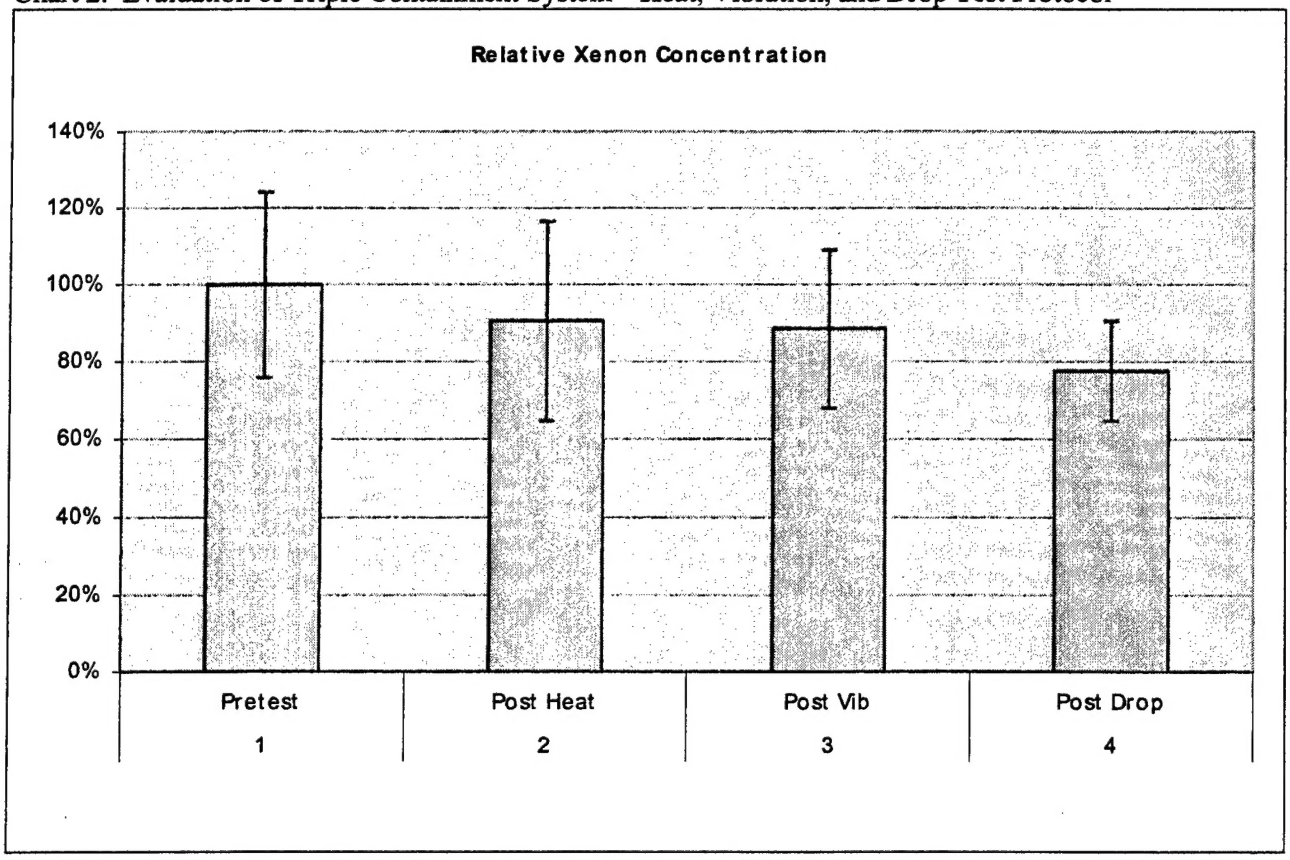


Chart 2. Evaluation of Triple Containment System – Heat, Vibration, and Drop Test Protocol



A4. Summary. In general, measurements do not demonstrate statistically significant changes in Xe-133 activity; thus suggesting leaks were not detected. The general downward trend noted between measurements in Chart 2 was also noted in the control BioSeal® bag. This could indicate either the presence of minor leaks or diffusion of xenon through the BioSeal® bag. Diffusion is suspected since the trend is comparable for both the [untested] control and the tested device(s); however, available data and experiment design were not sufficient for conclusive determination.